

Notice of Allowability

Application No.

10/721,253

Examiner

Maureen M. Wallenhorst

Applicant(s)

SAMSOONDAR, JAMES

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment and terminal disclaimer received on March 14, 2006.
2. ☒ The allowed claim(s) is/are 1-8, 11, 14-18, 21-32, 9, 12, 19, 10, 13, 20, 33-44, 52-60, 63-66, 61-62, 97 (renumbered 1-60).
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/147,373.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dawn Russell on May 19, 2006.

Claims 4, 12, 13, 19, 20, 33, 43 and 44 were changed as follows:

4. (Currently amended) The method of claim 2, wherein said one or more one analyte is an indicator of hemolysis, and in said step of measuring (step i)) said spectral segment is selected from wavelengths of said absorbance spectra of from about 550 nm to about 650 nm, said indicator of hemolysis selected from the group consisting of total hemoglobin (total Hb), oxy-hemoglobin (Oxy-Hb) ~~Oxy-Hb~~, and "total hemoglobin minus met-hemoglobin" ("total Hb minus met-Hb").

12. (Currently amended) The method of claim 9, wherein said quality control material comprises one or more than one of a perfluorocarbon-like blood substitute, and a lipid emulsion, and further comprises one or more than one substance, said one or more than one substance selected from the group consisting of a dye, copper sulfate, total hemoglobin (total-Hb), oxy-hemoglobin (Oxy-Hb), carboxy-hemoglobin (carboxy-Hb), "total hemoglobin minus met-hemoglobin" ("total

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Hb minus met-Hb"), cyanmet-hemoglobin (cyanmet-Hb), and a hemoglobin-based blood substitute, ~~a lipid emulsion, and a perfluorocarbon-like blood substitute.~~

13. (Currently amended) The method of claim 10, wherein said quality control material comprises one or more than one of a perfluorocarbon-like blood substitute, and a lipid emulsion, and further comprises one or more than one substance, said one or more than one substance selected from the group consisting of a dye, copper sulfate, total hemoglobin (total-Hb), oxy-hemoglobin (Oxy-Hb), carboxy-hemoglobin (carboxy-Hb), "total hemoglobin minus met-hemoglobin" ("total Hb minus met-Hb"), cyanmet-hemoglobin (cyanmet-Hb), and a hemoglobin-based blood substitute, ~~a lipid emulsion, and a perfluorocarbon-like blood substitute.~~

19. (Currently amended) A reagentless method for determining the concentration of one or more than one ~~analyte~~ of a perfluorocarbon-like blood substitute, turbidity, or a combination thereof in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

- i) monitoring calibration of said apparatus as defined in claim 9;
- ii) measuring absorbance values of said sample;
- iii) calculating an order derivative of absorbance of said sample; and
- iv) calculating a concentration of one or more than one of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion, by applying said primary calibration algorithm to said

order derivative of absorbance value.

20. (Currently amended) A reagentless method for determining the concentration of one or more than one ~~analyte~~ of a perfluorocarbon-like blood substitute, turbidity, or a combination thereof in a sample in a spectrophotometric apparatus comprising at least one primary calibration algorithm comprising:

- i) monitoring calibration of said apparatus as defined in claim 10;
- ii) measuring absorbance values of said sample;
- iii) calculating an order derivative of absorbance of said sample; and
- iv) calculating a concentration of one or more than one of said perfluorocarbon-like blood substitute, said turbidity, or a combination thereof, wherein said turbidity is measured in concentration units of a lipid emulsion, by applying said primary calibration algorithm to said order derivative of absorbance value.

33. (Currently amended) A method for selecting one or more than one substance as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus comprising:

- i) identifying a principal calibration wavelength for each of one or more than one substance;
- ii) measuring absorbance spectra of said one or more than one substance; and
- iii) selecting one or more than one of said one or more than one substance exhibiting a negative slope in said absorbance spectra, for a continuous spectral segment from about 5 nm to about 200 nm in length, said spectral segment including said principal calibration wavelength for each of

said one or more than one substance.

43. (Currently amended) A method for selecting one or more than one substance as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more than one of a perfluorocarbon-like blood substitute and turbidity, wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more than one of said perfluorocarbon-like blood substitute and said turbidity;
- ii) measuring absorbance spectra of said one or more than one substance; and
- iii) selecting one or more than one of said one or more than one substance exhibiting an absorbance value within the range from about 700 nm to about 1100 nm, wherein said range includes said principal calibration wavelength for one or more than one of said perfluorocarbon-like blood substitute and said turbidity.

44. (Currently amended) A method for selecting one or more than one substance as a quality control material for monitoring at least one primary calibration algorithm on a spectrophotometric apparatus for one or more than one of a perfluorocarbon-like blood substitute and turbidity, wherein turbidity is measured in terms of concentration units of a lipid emulsion, comprising:

- i) identifying a principal calibration wavelength for each of one or more than one of said perfluorocarbon-like blood substitute and said turbidity;

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- ii) measuring absorbance spectra of said one or more than one substance; and
- iii) selecting one or more than one of said substances exhibiting absorbance spectra as having a negative slope for a continuous spectral segment from about 5 nm to about 400 nm in length within the range of wavelengths from about 700 nm to about 1100 nm, wherein said range includes said principal calibration wavelength for one or more than one of said perfluorocarbon-like blood substitute and said turbidity.

2. The following is an examiner's statement of reasons for allowance: Application serial no. 10/721,253 is being allowed in view of the appropriately filed terminal disclaimer received on March 14, 2006. The attorney who signed the terminal disclaimer, Dawn Russell (reg. #44,751), is the same as the original attorney of record, Dawn Hayes, since the registration numbers for both names are the same, thereby indicating that it is the same person. In addition, when speaking on the phone with Dawn Russell to gain approval for the Examiner's Amendment, she confirmed that her name was recently legally changed, and that she also filed the name change with the Office of Enrollment and Discipline. Application serial no. 10/721,253 is also being allowed since none of the prior art of record teaches or fairly suggests a method of monitoring the calibration of a spectrophotometric apparatus comprising one or more calibration algorithms for one or more analytes comprising the steps of measuring the absorbance of a quality control material with the apparatus to obtain a measurement, calculating one or more values from the measurement using the one or more calibration algorithms, and comparing the one or more values to an assigned value given to the quality control material for each of the one or more analytes, wherein the quality control material exhibits an absorbance spectrum characterized as

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having a negative slope for a spectral segment having a length of 5-200 nm, and wherein the spectral segment includes a principal calibration wavelength for the one or more analytes. In addition, none of the prior art of record teaches or fairly suggests a reagentless method for determining the concentration of one or more analytes in a sample in a spectrophotometric apparatus containing calibration algorithms monitored by the above-described method, a method of selecting one or more substances as a quality control material for monitoring the calibration algorithms in a spectrophotometric apparatus, wherein the quality control material exhibits a negative slope for an analyte spectral segment between 5-200 nm in length, and a quality control material containing therein one or more substances that have a combined absorption spectrum with a negative slope for one or more spectral segments of between 5-200 nm in length.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
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mmw

May 19, 2006

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